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# Guidance for the Reregistration of Pesticide Products Containing Perfluidone as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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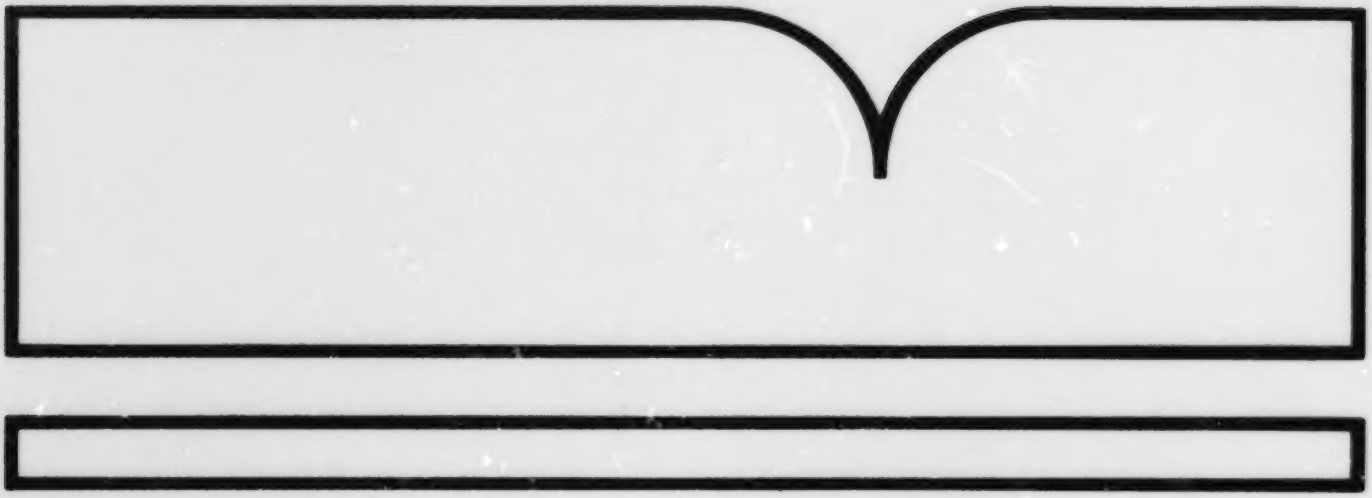

U.S. Department of Commerce
National Technical Information Service
NTIS.

PB86-173879

# GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

PERFLUIDONE

CASE NUMBER 195

CAS 37924-13-2

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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## INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available from the National Technical Information Service, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers

of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

| PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM | ACTION(S) REQUIRED TO MAINTAIN REGISTRATION |
|---|---|
| I. Products That Do Not Qualify For The Formulator's Exemption | - |
| A. Single Active Ingredient Products* | These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document. |
| B. Multiple Active Ingredient Products | These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required. |
| II. Products That Do Qualify For The Formulator's Exemption | Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices. |

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

# I. REGULATORY ASSESSMENT

## A. INTRODUCTION

This Registration Standard describes the regulatory position and rationale of the Environmental Protection Agency ("the Agency") for all registered manufacturing-use products (MPs) and end-use products (EPs) containing perfluidone as the sole active ingredient. The Agency bases its position and rationale on an evaluation of all MPs and Section 3 uses registered for perfluidone. EPs are reviewed only when there are no MPs registered or when the label has been changed significantly from the current accepted label. Mixtures are included only when there is a significant change in the label. After briefly describing the chemical and its uses, this chapter presents the Agency's regulatory position and rationale, the criteria for registration, acceptable ranges and limits, labeling requirements and the tolerance reassessments for perfluidone.

## B. DESCRIPTION OF CHEMICAL

Perfluidone is the accepted common name for the compound: 1,1,1,-trifluoro-N-[2-methyl-4-(phenylsulfonyl)phenyl] methanesulfonamide, as determined by the British Standards Institution, International Organization for Standardization, and the Weed Science Society of America. PERFLUIDONE is marketed under the trade name Destun®. The Chemical Abstracts Service (CAS) Registry number is 37924-13-2. The Office of Pesticide Program's EPA Chemical Code Number is 108001.

Perfluidone is a solid at room temperature and is odorless. The empirical formula is $C_{14}H_{12}F_3NO_4S_2$, and its molecular weight is 379.40. The melting point is 143-145°C. Perfluidone is soluble in aromatic and chlorinated hydrocarbon solvents; and in water (at 22°C) to 60.0 ug/ml.

Perfluidone is a selective preemergence herbicide registered for control of nutsedge species, certain grasses, and broadleaf weeds in flue-cured tobacco.

Perfluidone is mobile in the xylem but is of limited mobility in the phloem. Its mode-of-action in the weed is inhibition of photosystem I of the photosynthetic process.

Perfluidone was patented by the 3M Company (US Patent No. 4,005,141) in 1974 and was first registered for use in 1976. Although perfluidone is registered in the United States, it has never been commercially manufactured or marketed up to the present time.

Perfluidone is a 50.0% wettable powder end-use product.

C. REGULATORY POSITION AND RATIONALE

Based on the review and evaluation of all available data and other relevant information on perfluidone, the Agency has made the following determinations:

1. The available data are insufficient to indicate that any of the risk criteria listed in § 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the use of perfluidone at the present time.

   Rationale: Available data show that perfluidone is not highly acutely toxic by the dermal and ocular routes of exposure: Toxicity Category III and II respectively.

   A 90-day dog feeding study showed liver disorders ( hepatic lesions, hepatocyte vacuolation, hyalin degeneration and biliary stasis) at the two highest dose levels (400 and 800 ppm).

   The absence of other toxicological data prevents the Agency from determining the acute, subacute and chronic effects of perfluidone. Given the lack of data, the most appropriate action is to move quickly to fill the data gaps. When data are submitted and reviewed, the Agency will determine the registrability of the affected use pattern.

   The Agency is requiring the following toxicological data: acute oral, acute inhalation, and dermal sensitization studies, a 21-day dermal study, a teratogenicity study in both the rat and rabbit, gene mutation in bacteria, gene mutation in mammalian cells in culture, chromosomal aberration analysis in mammalian cells in culture, and DNA damage in mammalian cells in culture.

2. The data base supporting the perfluidone tolerance on cottonseed (0.01 ppm) has been reviewed and found to be inadequate. However, the data tables in the perfluidone registration standard will not include these data gaps attributable to the tolerance on cottonseed: § 158.135 Toxicology, Subchronic Testing (82-4), Chronic Testing (83-1, 83-2, 83-4), Special Testing (85-1); § 158.125 Residue Chemistry, Livestock (171-4), Animal Residues (171-4), Cottonseed (171-4) and Meat/Milk/Poultry/Eggs (171-4). Instead, the Agency will issue a Proposed Rule to revoke the perfluidone tolerance on cottonseed. If there is no response to support the tolerance, the Agency will issue a Notice of Tolerance Revocation.

Rationale: When data are lacking to support a tolerance, the normal procedure is to require the necessary data through the registration standard. If the registrant does not agree to develop the data to support the tolerance, the use of the product for which the tolerance was established would be suspended. In this case, the 3M Company is the sole registrant of perfluidone in the United States. Although initially registered for use on cotton, the product has never been marketed for that use. In July 1984, perfluidone's registration on cotton was voluntarily cancelled so this pesticide chemical no longer retains a registered food or feed crop use. Therefore the Agency will not require data necessary to support the tolerance at this time, but instead will publish a Proposed Rule to revoke the tolerance for perfluidone on cottonseed and allow 60 days for anyone wishing to support the tolerance to identify themselves. If there is no response to support the tolerance, the Agency will issue a Notice of Tolerance Revocation.

3. Products which are substantially similar to the registered end-use product may be considered for registration, subject to the terms and conditions specified in this document. However, the Agency will not register new products or new uses that would significantly increase exposure until such time as the data identified in this registration standard have been received and reviewed by the Agency.

Rationale: Under FIFRA Sections 3(c)(2)(B), 3(c)(5) and 3(c)(7), the Agency has the authority to require registrants and applicants for registration to provide data needed to support new or existing registrations. The issuance of this registration standard is the mechanism which the Agency has chosen to identify such data. These data will be reviewed and evaluated when they are received. At that time, the Agency will determine how the data will affect the registration of perfluidone.

4. EP labels will be required to bear a revised environmental hazard statement (See Section F. Labeling Requirements).

Rationale: Since the minimum data requirements for avian and freshwater invertebrate species are lacking, the environmental hazard statement is necessary to protect the non-target species.

5. EP labels will be required to maintain a rotational crop restriction (See Section F. Labeling Requirements).

Rationale: Because of a lack of data regarding persistence and mobility, it is not clear whether crops planted in soils treated with perfluidone would acquire illegal and perhaps harmful residues. To prevent this possibility, the rotational crop restriction will be maintained until such time as data are received and reviewed by the Agency. Then the Agency will decide what an appropriate restriction, if any, should be.

6. EP labels will be required to bear protective clothing statements for mixers, loaders, and applicators (See Section F. Labeling Requirements).

Rationale: Perfluidone is an eye irritant and a perfluidone 90-day study showed liver disorders in dogs. These effects and the absence of certain acute, subacute and chronic toxicity data on perfluidone necessitate a statement to protect the mixers, loaders, and applicators from undue exposure to the pesticide.

7. MP labels will be required to bear a statement regarding discharge to bodies of water and sewer systems.

Rationale: These precautions will minimize the discharge of effluents from manufacturing plants and also meet the Effluent Guideline requirements.

8. The Agency will not require a ground water advisory statement at this time. If data indicate that perfluidone may cause ground water concerns, the Agency may reconsider this decision.

Rationale: Although perfluidone is mobile in sandy loam, loamy sand, silt loam and clay loam soils, the Agency will not require a ground water advisory statement at this time. Perfluidone has never been commercially manufactured or sold in the United States and has not been identified in ground water. Environmental chemistry data are needed to characterize perfluidone's potential to contaminate ground water. If the data listed below show that perfluidone is persistent such that contamination of ground water may occur, the Agency may reconsider this decision.

The Agency will require the following environmental fate data: hydrolysis (§161-1), photodegradation in water (§161-2), aerobic soil metabolism (§162-1), and mobility (§163-1).

9. No endangered species label statements are required.

Rationale: Perfluidone was reviewed by the Agency under the endangered species cotton cluster, but it did not exceed any trigger. On flue-cured tobacco, if the maximum rate of 1.5 pounds active ingredient/acre were applied to six inches of water, the resulting residues (0.754 ppm) are less than 0.900 ppm (1/20 of the $LC_{50}$ of the most sensitive fish). Therefore, perfluidone's use on tobacco is not expected to adversely affect endangered species.

Currently, there are no available data for aquatic invertebrates or avain species.

10. The Agency is not requiring a reentry interval for the registered use of perfluidone.

Rationale: Perfluidone has low dermal toxicity (Category III) and it is a moderate eye irritant. Additionally, the single preemergence use per season of perfluidone on flue-cured tobacco is less likely to lead to reentry exposure.

D. CRITERIA FOR REGISTRATION UNDER THIS DOCUMENT

To be subject to this guidance document, MPs must meet the following conditions:

1. Contain perfluidone as the sole active ingredient and,

2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section E of this document.

Registration of products subject to this document must comply with all terms and conditions described in it, including commitment to fill data gaps on a schedule acceptable to EPA and consistent with that required of the present registrant. All registrants and applicants for registration under this document must follow the instructions contained in this document and complete and submit the appropriate forms within the specified time.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 50.0 percent perfluidone as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the MPs must be substantially similar to that in the currently registered product. Any MP not meeting these requirements will be considered a new product and will not be registerable under this guidance document.

2. Acute Toxicity Limits

The Agency will consider registration of products containing perfluidone, provided that the product labeling bear appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns:

To be registered under this standard, MPs containing perfluidone must be labeled for formulation only into end-use herbicide products for the commodity listed below.

Perfluidone is a selective preemergence herbicide registered for control of nutsedge species, certain grasses, and broadleaf weeds in flue-cured tobacco.

F. REQUIRED LABELING

All technical grade products, MPs, and EPs containing perfluidone must bear appropriate labeling as specified in 40 CFR § 162.10. Other portions of this guidance package contain specific information regarding label requirements.

In addition to the requirements stated in 40 CFR § 162.10, the following information must appear on the labeling of all products released for shipment after October 30, 1986, and products in the channels of trade after October 30, 1987.

1. Ingredient Statement

The ingredient statement for MPs and EPs must list the active ingredient as:

Perfluidone: 1,1,1,trifluoro-N-[2-methyl-4-(phenylsulfonyl) phenyl]methanesulfonamide, .....%

2. Precautionary Statements

Manufacturing-Use Product Statements

All products intended for formulation into EPs must bear the following environmental hazard statement:

"Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency".

End-Use Product Statements

The following environmental hazard statement must appear on all EPs:

"Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of waste".

The following rotational crop restriction statement must appear on all EPs:

"Limitations: Replant only tobacco in DESTUN® herbicide-treated soil during the year of application and the following crop year".

The following protective clothing statement must appear on all EPs:

"During mixing/loading or application, wear gloves impermeable to perfluidone. When handling the concentrated product, wear a dust mask and chemical resistant apron in addition to the gloves. Wash hands thoroughly with soap and water after handling and before eating, urinating, or smoking. Remove and wash clothing before reuse. Clothing should be laundered separately from household articles. Replace gloves frequently. Used gloves and clothing which has been drenched or heavily contaminated should be disposed of in accordance with state or local regulations".

G. TOLERANCE REASSESSMENT

The perfluidone registration on cotton was voluntarily-cancelled in July 1984, but the established tolerance on cottonseeds has not been revoked. Later this year, the Agency will notify the registrant that it must decide whether it wants to retain the tolerance on cotton or have the tolerance revoked.

The Agency is not conducting a tolerance reassessment on perfluidone because the current use on flue-cured tobacco is a non-food and non-feed use which does not require a tolerance. Therefore, the Agency will not require residue chemistry data on the metabolism of perfluidone and related metabolite(s) in crops and animals.

In the United States, a tolerance is currently established in 40 CFR § 180.165 for the residues of the herbicide, perfluidone: 1,1,1,trifluoro-N-[2-methyl-4-(phenylsulfonyl)phenyl] methanesulfonamide, in or on the following raw agricultural commodity:

| Commodity | Parts per million |
|---|---|
| Cottonseed | 0.01 |

International Tolerances

Presently, there are no tolerances for residues of perfluidone on cottonseed in Canada, Mexico, or in the Codex Alimentarius.

## REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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[1/] Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

[2/] The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

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(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

## III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Guideline Citation and Name of Test | Test Substance1/ | Guidelines Status2/ | Are Data Required Yes | Are Data Required No | Footnote Number or Citation | Data Must Be Submitted Within Time Frames Listed Below3/ |
|---|---|---|---|---|---|---|
| §158.120 Product Chemistry | | | | | | |
| Product Identity: | | | | | | |
| 61-1 - Product Identity and Disclosure of Ingredient | TGAI | R | [ ] | [X] | 00038230 | |
| 61-2 - Description of Beginning Materials and Manufacturing Process | TGAI | R | [X] | [ ] | | 6 months |
| 61-3 - Discussion of Formation of Impurities | TGAI | R | [X] | [ ] | | 6 months |
| Analysis and Certification of Product Ingredients | | | | | | |
| 62-1 - Preliminary Analysis | TGAI | CR | [X] | [ ] | 00038231 00038238 | 12 months 5/ |
| 62-2 - Certification of Limits | TGAI | CR | [X] | [ ] | | 12 Months |
| 62-3 - Analytical Method for Enforcement of Limits | TGAI | CR | [X] | [ ] | 00038237, 00038234 00038236 | 12 Months 5/ |
| Physical and Chemical Characteristics | | | | | | |
| 63-2 - Color | TGAI | R | [ ] | [X] | 00038230 | |
| 63-3 - Physical State | TGAI | R | [ ] | [X] | 00038230 | |
| 63-4 - Odor | TGAI | R | [ ] | [X] | 00038230 | |
| 63-5 - Melting Point | TGAI | R | [ ] | [X] | 00038230 | |
| 63-6 - Boiling Point | TGAI | R | [ ] | [X] | 00038230 | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Guideline Citation and Name of Test | Test Substance1/ | Guidelines Status2/ | Are Data Required Yes | Are Data Required No | Footnote Number or Citation | Data Must Be Submitted Within Time Frames Listed Below3/ |
|---|---|---|---|---|---|---|
| §158.120 Product Chemistry (Continued) | | | | | | |
| Physical and Chemical Characteristics (Continued) | | | | | | |
| 63-7 - Density, Bulk Density, or Specific Gravity | TGAI | R | [X] | [ ] | | 6 months |
| 63-8 - Solubility | TGAI or PAI | R | [ ] | [X] | 00038230 | |
| 63-9 - Vapor Pressure | PAI | R | [ ] | [X] | 00038230 | |
| 63-10 - Dissociation constant | PAI | R | [ ] | [X] | 00038230 | |
| 63-11 - Octanol/water partition coefficient | PAI | R | [ ] | [X] | 00038230 | |
| 63-12 - pH | TGAI | R | [X] | [ ] | | 6 months |
| 63-13 - Stability | TGAI | R | [ ] | [X] | 00038230 | |
| Other Requirements: | | | | | | |
| 64- 1 - Submittal of samples | TGAI, PAI | CR | [ ] | [X] | 4 | |

1/ TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient,
2/ R = Required; CR = Conditionally Required,
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
6 Month Due Date is March 30, 1986.
12 Month Due Date is September 30, 1986.
4/ This compound does not require the submittal of samples at this time.
5/ Data requirements are partially satisfied, but these data cannot stand on their own merits.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirements | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission 2/ |
|---|---|---|---|---|
| §158.125 Residue Chemistry | | | | |
| 171-2 - Chemical Identity | TGAI | Yes | 00038230 | No |
| 171-3 - Directions for Use | | Yes | | No |
| 171-4 - Nature of Residue (Metabolism) | | | | |
| - Plants | PAIRA | Yes | 00035510, 00039311 00039578, 00039579 00088387, 00105868 | No |
| - Livestock | PAIRA and Plant Metabolites | Yes | 00038253 | No |
| 171-4 - Residue Analytical Method | | | | |
| - Plant residues | TGAI and Metabolites | Yes | 00038524, 00039318 00039314, 00039491 00039315, 00077842 00039316, 00088388 | No |
| - Animal residues | TGAI and Metabolites | No | | No 3/ |
| 171-4 - Storage Stability Data | PAI | Yes | 00039317 | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirements | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission 2/ |
|---|---|---|---|---|
| §158.125 Residue Chemistry - Continued | | | | |
| 171-4 - Magnitude of the Residue-Residue Studies for Each Food Use<br>- Crop Group: Miscellaneous Commodities | | | | |
| o Tobacco | | | | |
| -- Non-Food/Feed | EP | Yes | 0088388, 00050732 GS0195-001 | No |
| -- Meat/Milk/Poultry/Eggs | TGAI or Plant Metabolites | No | | No 3/ |
| 171-5 - Reduction of Residue | Residue of Concern | No | | No 3/ |
| 171-6 - Proposed Tolerance | Residue of Concern | No | | No 3/ |
| 171-7 - Reasonable Grounds in Support of Petition | -- | No | | No 3/ |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

§158.125 Residue Chemistry - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
3/ These data are not required for perfluidone because of its non-food and non-feed use pattern.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.130 Environmental Fate | | | | | | |
| DEGRADATION STUDIES-LAB: | | | | | | |
| 161-1 - Hydrolysis | TGAI or PAIRA | B | No | - | Yes | 9 months |
| Photodegradation | | | | | | |
| 161-2 - In water | TGAI or PAIRA | B | No | - | Yes | 9 months |
| 161-3 - On soil | TGAI or PAIRA | B | No | | No 6/ | |
| 161-4 - In Air | TGAI or PAIRA | | No | | No 6/ | |
| METABOLISM STUDIES-LAB: | | | | | | |
| 162-1 - Aerobic Soil | TGAI or PAIRA | B | No | - | Yes | 27 months |
| 162-2 - Anaerobic Soil | TGAI or PAIRA | B | No | | No 6/ | |
| 162-3 - Anaerobic Aquatic | TGAI or PAIRA | | No | | No 6/ | |
| 162-4 - Aerobic Aquatic | TGAI or PAIRA | | No | | No 6/ | |
| MOBILITY STUDIES: | | | | | | |
| 163-1 - Leaching and Adsorption/Desorption | TGAI or PAIRA | B | No | - | Yes 4/ | 12 months |
| 163-2 - Volatility (Lab) | TEP | | No | | No 6/ | |
| 163-3 - Volatility (Field) | TEP | | No | | No 6/ | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.130 Environmental Fate - Continued | | | | | | |
| DISSIPATION STUDIES-FIELD: | | | | | | |
| 164-1 - Soil | TEP | B | No | - | Yes | 27 months |
| 164-2 - Aquatic (Sediment) | TEP | | No | | No 6/ | |
| 164-3 - Forestry | TEP | | No | | No 6/ | |
| 164-4 - Combination and Tank Mixes | TEP | | No | | No 5/ | |
| 164-5 - Soil, Long-term | TEP | B | No | | No 6/ | |
| ACCUMULATION STUDIES: | | | | | | |
| 165-1 - Rotational Crops (Confined) | PAIRA | B | No | | No 6/ | |
| 165-2 - Rotational Crops (Field) | TEP | B | No | | No 6/ | |
| 165-3 - Irrigated Crops | TEP | | No | | No 6/ | |
| 165-4 - In Fish | TGAI or PAIRA | B | No | | No 6/ | |
| 165-5 - In Aquatic Non-Target Organisms | TEP | | No | | No 6/ | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

§158.130 Environmental Fate - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 9 Month Due Date is June 30, 1986.
- 12 Month Due Date is September 30, 1986.
- 27 Month Due Date is December 30, 1987.

4/ Additional data will be required on leaching of perfluidone degradation products.
5/ Data on perfluidone in combination and tank mixes are not addressed in this Guidance Document.
6/ These data requirements do not apply to the current use pattern.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Time Frame for Data Submission 3/ |
|---|---|---|---|---|---|---|
| §158.135 Toxicology | | | | | | |
| ACUTE TESTING: | | | | | | |
| 81-1 - Acute Oral Toxicity - Rat | TGAI | B | No | - | Yes | 9 months |
| 81-2 - Acute Dermal Toxicity - Rabbit | TGAI | B | Yes | 00038242 | No | |
| 81-3 - Acute Inhalation Toxicity - Rat | TGAI | B | No | - | Yes | 9 months |
| 81-4 - Primary Eye Irritation | TGAI | B | Yes | 00038244 | No | |
| 81-5 - Primary Skin Irritation | TGAI | B | Yes | 00038244 | No | |
| 81-6 - Dermal Sensitization | TGAI | B | No | - | Yes | 9 months |
| 81-7 - Delayed Neurotoxicity - Hen | TGAI | B | No | | No 4/ | |
| SUBCHRONIC TESTING: | | | | | | |
| 82-1 - 90-Day Feeding : - Rodent, and | TGAI | B | No | - | No 7/ | |
| - Non-rodent (Dog) | TGAI | B | Yes | 00035574 | No | |
| 82-2 - 21-Day Dermal - Rabbit | TGAI | B | No | - | Yes | 12 months |
| 82-3 - 90-Day Dermal - Rabbit | TGAI | B | No | | No 7/ | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.135 Toxicology - Continued | | | | | | |
| 82-4 - 90-Day Inhalation: - Rat | TGAI | B | No | | No 7/ | |
| 82-5 - 90-Day Neurotoxicity: - Hen | TGAI | B | No | | No 4/ | |
| -Mammal | TGAI | B | No | | No 4/ | |
| CHRONIC TESTING: | | | | | | |
| 83-1 - Chronic Toxicity - 2 species: - Rodent, and | TGAI | B | No | | No 7/ | |
| - Non-rodent (Dog) | TGAI | B | No | | No 7/ | |
| 83-2 - Oncogenicity - 2 species: - Rat (preferred), and | TGAI | B | No | | No 7/ | |
| - Mouse (preferred) | TGAI | B | No | | No 7/ | |
| 83-3 - Teratogenicity - 2 species: - Rat | TGAI | B | No | - | Yes 5/ | 15 Months |
| - Rabbit | TGAI | B | No | - | Yes 5/ | 15 Months |
| 83-4 - Reproduction - Rat 2-generation | TGAI | B | No | | No 7/ | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.135 Toxicology - Continued | | | | | |
| MUTAGENICITY TESTING | | | | | |
| 84-2 - Gene Mutation (Ames Test) | TGAI | B | No | - | Yes 6/ 9 months |
| 84-2 - Structural Chromosomal Aberration | TGAI | B | No | - | Yes 6/ 12 months |
| 84-4 - Other Genotoxic Effects | TGAI | B | No | - | Yes 6/ 12 months |
| SPECIAL TESTING | | | | | |
| 85-1 - General Metabolism | PAI or PAIRA | B | No | | No 7/ |
| 85-2 - Dermal Penetration | Choice | B | No | | No 7/ |
| 86-1 - Domestic Animal Safety | Choice | B | No | | No 7/ |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

§158.135 Toxicology - Continued

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document....
- 9 Month Due Date is June 30, 1986 .
- 12 Month Due Date is September 30, 1986 .
- 15 Month Due Date is December 30, 1986.

4/ Perfluidone is not an organophosphate, nor is it known to cause delayed neurotoxicity.
5/ Teratology studies in both the rat and rabbit are required.
6/ The following mutagenicity data are required:
a. In vitro mammalian cell point mutation [L5178Y (TK), or CHO (HGPRT), or V79 (HGPRT)] tests,
b. In vitro cytogenetic damage: both chromosomal aberration and SCE (in CHO cells, or human lymphocytes, or other rodent/human cell lines/strains tests,
c. In vitro/in vivo primary hepatocyte repair for UDS testing both in vivo and in vitro exposure of cells to Perfluidone,
d. In vivo cytogenetics test for chromosomal aberrations using bone marrow preparations of rats,
e. Dominant lethal test in rats or mice.

7/ The guidelines and use pattern indicate that these data are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use 2/ Pattern | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.140 Reentry Protection | | | | | |
| 132-1 - Foliar Dissipation | TEP | B | No | | No 4/ |
| 132-1 - Soil Dissipation | TEP | B | No | | No 4/ |
| 133-3 - Dermal Exposure | TEP | B | No | | No 4/ |
| 133-4 - Inhalation Exposure | TEP | B | No | | No 4/ |
| §158.142 Spray Drift | | | | | |
| 201-1 - Droplet Size Spectrum | TEP | B | No | | No 5/ |
| 201-1 - Drift Field Evaluation | TEP | B | No | | No 5/ |

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
4/ Based on the criteria cited in 40 CFR §158.140, reentry data are not required for perfluidone.
5/ These data requirements do not apply to perfluidone's use pattern.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Time Frame for Data Submission 3/ |
|---|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms | | | | | | |
| AVIAN AND MAMMALIAN TESTING | | | | | | |
| 71-1 - Acute Avian Oral Toxicity | TGAI | B | No | - | Yes | 9 Months |
| 71-2 - Avian Subacute Dietary Toxicity | | | | | | |
| - Upland Game Bird, and | TGAI | B | No | - | Yes | 9 Months |
| - Waterfowl | TGAI | B | No | - | Yes | 9 Months |
| 71-3 - Wild Mammal Toxicity | TGAI | B | No | | No 7/ | |
| 71-4 - Avian Reproduction | | | | | | |
| - Upland Game Bird, and | TGAI | B | Reserved | | 4/ | |
| - Waterfowl | TGAI | B | Reserved | | 4/ | |
| 71-5 - Simulated Field Testing | | | | | | |
| - Mammals, and | TEP | B | No | | No 7/ | |
| - Birds | TEP | B | No | | No 7/ | |
| - Actual Field Testing | | | | | | |
| - Mammals, and | TEP | B | No | | No 7/ | |
| - Birds | TEP | B | No | | No 7/ | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ | |
|---|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms - Continued | | | | | | |
| AQUATIC ORGANISM TESTING | | | | | | |
| 72-1 - Freshwater Fish Toxicity - Warmwater Fish Species, | TGAI | B | Partially 5/6/ | 00039574 | Yes | 9 months |
| | TEP | B | No | | No 7/ | |
| - Coldwater Fish Species | TGAI | B | Partially 5/6/ | 00039574 | Yes | 9 months |
| | TEP | B | No | | No 7/ | |
| 72-2 - Acute Toxicity to Freshwater Invertebrates | TGAI | B | No | - | Yes | 9 months |
| | TEP | B | No | | No 7/ | |
| 72-3 - Acute Toxicity to Estuarine and Marine Organisms | | | | | | |
| - Marine Fish | TGAI | B | No | | No 7/ | |
| - Mollusk | TGAI | B | No | | No 7/ | |
| - Shrimp | TGAI | B | No | | No 7/ | |
| 72-4 - Fish Early Life Stage, and | TGAI | B | No | | No 7/ | |
| - Aquatic Invertebrate Life-Cycle | TGAI | B | No | | No 7/ | |
| 72-5 - Fish - Life-Cycle | TGAI | B | No | | No 7/ | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms - Continued | | | | | |
| 72-6 - Aquatic Organism Accumulation | TGAI, PAI OR Degradation Product | | | | |
| - Crustacean | | B | No | | No 7/ |
| - Fish | | B | No | | No 7/ |
| - Insect Nymph | | B | No | | No 7/ |
| - Mollusk | | B | No | | No 7/ |
| 72-7 - Simulated Field Testing - Aquatic Organisms | TEP | B | No | | No 7/ |
| - Actual Field Testing -Aquatic Organisms | TEP | B | No | | No 7/ |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
° 9 Month Due Date is June 30, 1986.
4/ Requirement is reserved pending acute avian data.
5/ Clarification is needed regarding solubility of the technical material.
6/ Present study can only fulfill requirement in conjunction with additional data.
7/ The guidelines and use pattern indicate that these data are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/ |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect | | | | | |
| NONTARGET INSECT TESTING - POLLINATORS: | | | | | |
| 141-1 - Honey bee acute contact toxicity | TGAI | B | No | - | No 4/ |
| 141-2 - Honey bee - toxicity of residues on foliage | TEP | B | No | | No 4/ |
| 141-4 - Honey bee subacute feeding study | (Reserved) 6/ | | | | |
| 141-5 - Field testing for pollinators | TEP | B | No | | No 5/ |
| NONTARGET INSECT TESTING - AQUATIC INSECTS: | | | | | |
| 142-1 - Acute toxicity to aquatic insects | (Reserved) 6/ | | | | |
| 142-1 - Aquatic insect life-cycle study | (Reserved) 6/ | | | | |
| 142-3 - Simulated or actual field testing for aquatic insects | (Reserved) 6/ | | | | |
| 143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES | (Reserved) 6/ | | | | |

TABLE A
GENERIC DATA REQUIREMENTS FOR PERFLUIDONE

§158.155 Nontarget Insects

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
4/ No additional data required because the proposed use pattern would not result in exposure of honey bees to perfluidone.
5/ No additional data required because the proposed use pattern would not result in exposure of other pollinators to perfluidone.
6/ Reserved pending Agencys' decision as to whether data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PERFLUIDONE a/

| Guideline Citation and Name of Test | Test Substance1/ | Guidelines Status2/ | Are Data Required Yes | Are Data Required No | Footnote Number or Citation | Data Must Be Submitted Within Time Frames Listed Below3/ |
|---|---|---|---|---|---|---|
| §158.120 Product Chemistry | | | | | | |
| Product Identity: | | | | | | |
| 61-1 - Product Identity and Disclosure of Ingredients | MP | R | [ ] | [X] | 00038230 | |
| 61-2 - Description of Beginning Materials and Manufacturing Process | MP | R | [X] | [ ] | | 6 months |
| 61-3 - Discussion of Formation of Impurities | MP | R | [X] | [ ] | | 6 months |
| Analysis and Certification of Product Ingredients | | | | | | |
| 62-1 - Preliminary Analysis | MP | CR | [X] | [ ] | | 12 months |
| 62-2 - Certification of Limits | MP | R | [X] | [ ] | | 12 months |
| 62-3 - Analytical Methods to Verify Certified Limit | MP | R | [X] | [ ] | | 12 months |
| Physical and Chemical Characteristics | | | | | | |
| 63-2 - Color | MP | R | [ ] | [X] | 00038230 | |
| 63-3 - Physical State | MP | R | [ ] | [X] | 00038230 | |
| 63-4 - Odor | MP | R | [ ] | [X] | 00038230 | |
| 63-5 - Melting Point | MP | R | [ ] | [X] | 00038230 | |
| 63-6 - Boiling Point | MP | R | [ ] | [X] | 00038230 | |

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PERFLUIDONE a/

| Guideline Citation and Name of Test | Test Substance 1/ | Guidelines Status 2/ | Are Data Required Yes | Are Data Required No | Footnote Number | Data Must Be Submitted Within Time Frames Listed Below 3/ |
|---|---|---|---|---|---|---|
| §158.120 Product Chemistry (Continued) | | | | | | |
| Physical and Chemical Characteristics (Continued) | | | | | | |
| 63-7 - Density, Bulk Density, or Specific Gravity | MP | R | [X] | [ ] | | 6 months |
| 63-12 - pH | MP | R | [X] | [ ] | | 6 months |
| Other Requirements: | | | | | | |
| 64- 1 - Submittal of samples | MP | CR | [ ] | [X] | 4 | |

§ 158.120 Product Chemistry

a/ Technical perfluidone also serves as a manufacturing-use product.
1/ TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient,
2/ R = Required; CR = Conditionally Required,
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
6 Month Due Date is March 30, 1986.
12 Month Due Date is September 30, 1986.
4/ This compound does not require the submittal of samples at the present time.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PERFLUIDONE

| Data Requirement | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? | Time Frame for Data Submission 2/ |
|---|---|---|---|---|---|
| §158.135 Toxicology | | | | | |
| ACUTE TESTING | | | | | |
| 81-1 - Acute Oral Toxicity - Rat | MP | No | - | Yes | 9 months |
| 81-2 - Acute Dermal Toxicity - Rabbit | MP | Yes | 00038242 | No | |
| 81-3 - Acute Inhalation Toxicity - Rat | MP | No | - | Yes | 9 months |
| 81-4 - Primary Eye Irritation - Rabbit | MP | Yes | 00038244 | No | |
| 81-5 - Primary Dermal Irritation - Rabbit | MP | Yes | 00038244 | No | |
| 81-6 - Dermal Sensitization - Guinea Pig | MP | No | - | Yes | 9 months |

§158.135 Toxicology - Continued

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.

° 9 Month Due Date is June 30, 1986 .

## IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

### A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

| Size of Label on Front Panel in Square Inches | Signal Word Minimum Type Size All Capitals | "Keep Out of Reach of Children" Minimum Type Size |
|---|---|---|
| 5 and under | 6 point | 6 point |
| above 5 to 10 | 10 point | 6 point |
| above 10 to 15 | 12 point | 8 point |
| above 15 to 30 | 14 point | 10 point |
| over 30 | 18 point | 12 point |

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

## Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing perfluidone as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing perfluidone in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing perfluidone alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. - End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing perfluidone either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Applications and other required information should be submitted to the following address:

Robert J. Taylor
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-1800

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

## Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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Citation

GS0195-001 U.S. Department of Agriculture (1983) Agricultural Statistics III. Tobacco: 97.

OMB Approval No. 2000-0468

| FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET | EPA REGISTRATION NO. |
|---|---|
| PRODUCT NAME | |
| APPLICANT'S NAME | DATE GUIDANCE DOCUMENT ISSUED |

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

| REGISTRANT'S AUTHORIZED REPRESENTATIVE | SIGNATURE | DATE |
|---|---|---|
| | | |

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-04C

## CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

*(To qualify, certify ALL four items)*

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

| NAME OF FIRM | EPA COMPANY NUMBER |
|---|---|
| | - |
| | |
| | |
| | |

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data: -

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

| NAME OF FIRM | DATE OF OFFER |
|---|---|
| | |
| | |
| | |
| | |

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

| TYPED NAME | SIGNATURE | DATE |
|---|---|---|
| | | |



EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

| Registration Guideline No. | Name of Test | Test not required for my product listed above (check below) | I am complying with data requirements by | | (For EPA Use Only) Accession Numbers Assigned |
|---|---|---|---|---|---|
| | | | Citing MRID# | Submitting Data (Attached) | |
| §158.20 PRODUCT CHEMISTRY | | | | | |
| 61-1 | Identity of ingredients | | | | |
| 61-2 | Statement of composition | | | | |
| 61-3 | Discussion of formation of ingredients | | | | |
| 62-1 | Preliminary analysis | | | | |
| 62-2 | Certification of limits | | | | |
| 62-3 | Analytical methods for enforcement limits | | | | |
| 63-2 | Color | | | | |
| 63-3 | Physical state | | | | |
| 63-4 | Odor | | | | |
| 63-5 | Melting point | | | | |
| 63-6 | Boiling point | | | | |
| 63-7 | Density, bulk-density, or specific gravity | | | | |
| 63-8 | Solubility | | | | |
| 63-9 | Vapor pressure | | | | |
| 63-10 | Dissociation constant | | | | |
| 63-11 | Octanol/water partition coefficient | | | | |
| 63-12 | pH | | | | |

| Registration Guideline No. | Name of Test | Test not required for my product listed above (check below) | I am complying with data requirements by | | (For EPA Use Only) Accession Numbers Assigned |
|---|---|---|---|---|---|
| | | | Citing MRID# | Submitting Data (Attached) | |
| 63-13 | Stability | | | | |
| 63-14 | Oxidizing/reducing reaction | | | | |
| 63-15 | Flammability | | | | |
| 63-16 | Explodability | | | | |
| 63-17 | Storage stability | | | | |
| 63-18 | Viscosity | | | | |
| 63-19 | Miscibility | | | | |
| 63-20 | Corrosion characteristics | | | | |
| 63-21 | Dielectric breakdown voltage | | | | |
| §158.135 TOXICOLOGY | | | | | |
| 81-1 | Acute oral LD-50, rat | | | | |
| 81-2 | Acute dermal LD-50 | | | | |
| 81-3 | Acute inhalation, LC-50 rat | | | | |
| 81-4 | Primary eye irritation, rabbit | | | | |
| 81-5 | Primary dermal irritation | | | | |
| 81-6 | Dermal sensitization | | | | |

§162.10 LABELING REQUIREMENTS

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during

the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

| Hazard indicators | Toxicity categories | | | |
|---|---|---|---|---|
| | I | II | III | IV |
| Oral $LD_{50}$ | Up to and including 50 mg/kg | From 50 thru 500 mg/kg | From 500 thru 5000 mg/kg | Greater than 5000 mg/kg |
| Inhalation $LC_{50}$ | Up to and including .2 mg/liter | From .2 thru 2 mg/liter | From 2 thru 20 mg/liter | Greater than 20 mg/liter |
| Dermal $LD_{50}$ | Up to and including 200 mg/kg | From 200 thru 2000 | From 2,000 thru 20,000 | Greater than 20,000 |
| Eye effects | Corrosive; corneal opacity not reversible within 7 days | Corneal opacity reversible within 7 days; irritation persisting for 7 days | No corneal opacity; irritation reversible within 7 days | No irritation |
| Skin effects | Corrosive | Severe irritation at 72 hours | Moderate irritation at 72 hours | Mild or slight irritation at 72 hours |

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

| Size of label front panel in square inches | Points | |
|---|---|---|
| | Required signal word, all capitals | "Keep out of reach of Children" |
| 5 and under . . . . . | 6 | 6 |
| Above 5 to 10 . . . . . | 10 | 6 |
| Above 10 to 15 . . . . . | 12 | 8 |
| Above 15 to 30 . . . . . | 14 | 10 |
| Over 30 . . . . . | 18 | 12 |

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

| Toxicity category | Precautionary statements by toxicity category | |
|---|---|---|
| | Oral, inhalation, or dermal toxicity | Skin and eye local effects |
| I . . . | Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]. | Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.] |
| II . . . | May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]. | Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]. |
| III . . . | Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]. | Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists. |
| IV . . . | [No precautionary statements required.]. | [No precautionary statements required.]. |

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or

damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral $LD_{50}$ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute $LC_{50}$ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral $LD_{50}$ of 100 mg/kg or less, or a subacute dietary $LC_{50}$ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

| Flash point | Required text |
|---|---|
| (A) PRESSURIZED CONTAINERS | |
| Flash point at or below 20°F; if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame. | Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| All other pressurized containers . . . . . | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| (B) NONPRESSURIZED CONTAINERS | |
| At or below 20°F . . . . . | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| Above 20°F and not over 80°F . . . . . | Flammable. Keep away from heat and open flame. |
| Above 80°F and not over 150°F . . . . . | Do not use or store near heat or open flame. |

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 1 | Product name | All products | Front panel | Center front panel | |
| 2 | Company name and address | All products | None | Bottom front panel or end of label text | If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc. |
| 3 | Net contents | All products | None | Bottom front panel or end of label text | May be in metric units in addition to U.S. units |
| 4 | EPA Reg. No. | All products | None | Front panel | Must be in similar type size and run parallel to other type. |
| 5 | EPA Est. No. | All products | None | Front panel, immediately before or following Reg. No. | May appear on the container instead of the label. |
| 6A | Ingredients statement | All products | Front panel | Immediately following product name | Text must run parallel with other text on the panel. |
| 6B | Pounds/gallon statement | Liquid products where dosage given as lbs. ai/unit area | Front panel | Directly below the main ingredients statement | |
| 7 | Front panel precautionary statements | All products | Front panel | | All front panel precautionary statements must be grouped together, preferably blocked. |
| 7A | Keep Out of Reach of Children (Child hazard warning) | All products | Front panel | Above signal word | Note type size requirements. |
| 7B | Signal word | All products | Front panel | Immediately below child hazard warning | Note type size requirements. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 7C | Skull & cross-bones and word POISON (in red) | All products which are Category I based on oral, dermal, or inhalation toxicity | Front panel | Both in close proximity to signal word | |
| 7D | Statement of practical treatment | All products in Categories I, II, and III | Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements. | Front panel for all. | |
| 7E | Referral statement | All products where precautionary labeling appears on other than front panel. | Front panel | | |
| 8 | Side/back panel precautionary statements | All products | None | Top or side of back panel preceding directions for use | Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked. |
| 8A | Hazards to humans and domestic animals | All products in Categories I, II, and III | None | Same as above | Must be preceded by appropriate signal word. |
| 8B | Environmental hazards | All products | None | Same as above | Environmental hazards include bee caution where applicable. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 8C | Physical or chemical hazards | All pressurized products, others with flash points under 150°F | None | Same as above | |
| 9A | Restricted block | All restricted products | Top center of front panel | Preferably blocked | Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word. |
| 9C | Misuse statement | All products | Immediately following heading of directions for use | | |
| 10A | Reentry statement | All cholinesterase inhibitors | In the directions for use | Immediately after misuse statement | |
| 10C | Storage and disposal block | All products | In the directions for use | Immediately before specific directions for use or at the end of directions for use | Must be set apart and clearly distinguishable from from other directions for use. |
| 10D | Directions for use | All products | None | None | May be in metric as well as U.S. units |

## PHYSICAL-CHEMICAL HAZARDS

| Criteria | Required Label Statement |
|---|---|
| I. Pressurized Containers | |
| A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening. | Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| C. ALL OTHER PRESSURIZED CONTAINERS | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| II. Non-Pressurized Containers | |
| A. Flashpoint at or below 20°F. | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| B. Flashpoint above 20°F and not over 80°F. | Flammable. Keep away from heat and open flame. |
| C. Flashpoint over 80°F and not over 150°F. | Do not use or store near heat and open flame. |
| D. Flashpoint above 150°F. | None required. |

## STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

| Size of label front panel in square inches | Required type size for the heading STORAGE AND DISPOSAL (all capitals) |
|---|---|
| 10 and under | .6 point |
| Above 10 to 15 | .8 point |
| Above 15 to 30 | 10 point |
| Over 30 | 12 point |

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

| Container Type | Statement |
|---|---|
| Non-aerosol products (bottles, cans, jars) | Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash. |
| Non-aerosol products (bags) | Do not reuse bag. Discard bag in trash. |
| Aerosol products | Replace cap and discard containers in trash. Do not incinerate or puncture. |

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

| Container Type | Statement |
|---|---|
| Metal containers (non-aerosol) | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. |
| Glass containers | Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures. |
| Fiber drums with liners | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner. |
| Paper and plastic bags | Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Compressed gas cylinders | Return empty cylinder for reuse (or similar wording) |

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene